

Agenda

Radiological Devices Advisory Panel Meeting

November 18, 2009

Purpose of the Meeting – To discuss 2 draft guidance documents for computer-aided-detection (CAD) devices.

Open Session

- 8:00-8:10 **Call to order and the Panel Introduction** – Panel Chair
 FDA Introductory Remarks – Executive Secretary
- 8:10-10:00 **FDA Presentation**
- Introduction
 - Background and History of Regulation of CADe Devices
 - Overview of Draft Guidance CADe Guidance Documents
- 10:00-10:15 **BREAK**
- 10:15-12:00 **FDA Presentation**
- Considerations in the Premarket Evaluation of CADe Devices
 - Epidemiologic review of use of CADe Devices
- 12:00-1:00 **LUNCH**
- 1:00-1:05 **Call to order** – Panel Chair
- 1:05-2:15 **Open Public Hearing:** interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.
- 2:15-3:15 **Panel Discussion of Draft Guidance Documents**
- 3:15-3:30 **BREAK**
- 3:30-5:15 **Panel Discussion and Questions to the Panel**
- 5:15-5:30 **Meeting Adjournment and Final Remarks** – Panel Chair

*** Open Public Hearings** – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.